



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

FDA Small Business and Industry Assistance Regulatory Education for Industry Fall Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) are sponsoring a 2 day conference entitled "FDA Small Business and Industry Assistance Regulatory Education for Industry (REdI) Fall Conference." The goal of this conference is to provide direct, relevant, and helpful information on the key aspects of drug and device regulations. Our primary audience is that of small manufacturers of drug and/or device medical products who want to learn about how FDA approaches the regulation of drugs and devices. However, anyone involved in the pharmaceutical and/device industry may attend.

DATES: The public conference will be held on September 27 and 28, 2016, from 8:15 a.m. to 4:15 p.m. See the SUPPLEMENTARY INFORMATION section for registration information.

ADDRESSES: The public conference will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Cypress and Magnolia Ballrooms (4th floor), Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Brenda Stodart, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6707, cdersbia@fda.hhs.gov; or Elias Mallis, Center for Devices and

Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-7100, DICE@fda.hhs.gov

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public conference entitled “FDA Small Business and Industry Assistance Regulatory Education for Industry (REdI) Fall Conference.” This conference is intended to increase the drug and device industry’s awareness of applicable FDA regulations. There will be an opportunity for questions and answers following each presentation.

II. Topics for Discussion at the Conference

- CDER: Manufacturing Process Validation; Interactions with FDA; Emerging Technology and Inspection for New Drug Applications and Biologic License Applications.
- CDRH: 510(k); De Novo; Design Controls; and Complaints.

Registration: There is no fee to attend the public conference. Space is limited, and registration will be on a first-come, first-served basis. To register, please complete registration at:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm514324.htm>.

If you need special accommodations due to disability, please contact info@sbiaevents.com at least 7 days in advance.

Streaming Webcast of the Conference: This public conference will also be Webcast. Persons interested in viewing the Webcast must register to receive a confirmation email with the Webcast link.

Transcripts: Transcripts will not be available.

Dated: August 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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